THE CLAIMS ARE NOT INDEFINITE

Claims 8-7, 10-15, 17-21, and 23-33 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses the rejection.

In regard to claim 8, the Examiner alleged that the claim is indefinite because it is unclear what constituent comprise each of the "structural component," "recruiting component," and "growth and/or maturation component." "Recruiting component" has been amended to recite "chemotactic component" in accordance with U.S. Pat. No. 5,932,207. Applicant avers that each of the other components is defined and described in the specification. "Structural component" is defined on page 1, second paragraph, which recites that " the structural component can consist, for example, of various types of collagen, elastin, or proteoglycans." The "growth or maturation component" is defined on page 1, last paragraph to page 2, first paragraph, which reads "at least one growth and/or maturation component, preferably in the form of one or several cytokines." The paragraph also went on to list examples of cytokines. Therefore, because "structural component" and "growth or maturation component" are well defined in and supported by the specification, the claims are not indefinite. Furthermore, the components have been amended to be in accord with the claims of U.S. Pat. No. 5,932,207.

In regard to claims 31-33, the Examiner alleged that the phrase "carrier is in the form of a body" is indefinite because it is not clear what "body" is supposed to be. Applicant has amended claims 31-33 to eliminate "is in the form of a body" in the Amendment filed **August 24, 2001**. This rejection, therefore, is moot.

THE CLAIMS ARE ENABLED

Claims 8-7, 10-15, 17-21, and 23-39 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabled for method of stimulating the formation of bones, does not reasonably provide enablement for the reproduction of bone and production of bone. Applicant respectfully traverses the rejection.

Applicant has amended the claims to recite "a composition." The preamble of a composition claim is generally non-limiting. *See* MPEP 2111.02. Further, during the interview on August 27, 2001, the Examiner agreed that the preamble of a composition claim would be given no patentable weight. Therefore, because the claims have been amended to recite "a composition," the rejection is no longer appropriate and should be withdrawn.

DOUBLE PATENTING

Claims 8-14 and 31 stand rejected under the judicially created doctrine of double patenting over claims 1-8 of U.S. Pat. No. 5,932,207. Applicant respectfully requests that the Examiner holds the rejection at abeyance until the claims are deemed allowable. At that time, Applicant will file a terminal disclaimer to overcome the rejection.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

Applicant has responded to the Office action mailed November 6, 2001. All of the claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME COMISKY & McCAULEY LLP, Deposit Account No. 23-2185 (109572-00101). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

Date: April 2, 2002

By: Herbert Cohen
Registration No. 25,109

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please cancel claims 36 and 37.

Please amend the claims as follows:

8. (Twice amended) [Means] A composition for the at least partial production or reproduction of bone comprising a carrier [which includes] selected from the group consisting of polymer, ceramic, metallic and nonmetallic materials; and an active ingredient complex, said active ingredient complex comprising at least one bone derived structural component, at least one bone derived [recruiting] chemotactic component, at least one bone derived adhesion component, and at least one bone derived growth [and/]or maturation component[; wherein said carrier is taken from the group consisting of polymer, ceramic, metallic and nonmetallic materials].

10. (Twice amended) [Means] A composition according to claim 8, wherein the ceramic carrier materials are selected from the group consisting of hydroxylapatite, calciumphosphate, aluminum oxide, and ionomer cement.

11. (Twice amended) [Means] A composition according to claim 8, wherein the metallic carrier material is titanium or titanium alloy.

12. (Twice amended) [Means] A composition according to claim 8, wherein the nonmetallic carrier material is carbon.

13. (Twice amended) [Means] A composition according to claim 8, wherein the polymer is derived from natural monomers taken from the group consisting of amino acids, [glutomic] glutamic acid, lactic acid, hydroacetic acid, and copolymers thereof.

14. (Twice amended) [Means] A composition according to claim 8, wherein the polymer is a polylactate.

15. (Twice amended) [Method] A method of producing, reproducing or stabilizing vertebral structures or of fixing endoprosthesis comprising the step of implanting a [means] composition according to claim 1 into living beings.

17. (Twice amended) [Method] A method according to claim 15, wherein the metallic carrier material is titanium or a titanium alloy.

18. (Twice amended) [Method] A method according to claim 15, wherein the nonmetallic carrier material is carbon.

19. (Twice amended) [Method] A method according to claim 15, wherein the ceramic carrier materials are selected from the group consisting of hydroxylapatite, calciumphosphate, aluminum oxide, and ionomer cement.

20. (Twice amended) [Method] A method according to claim 15, wherein the carrier is an endoprosthesis.

21. (Twice amended) [Method] A method of treating osteoporosis and pseudoarthrosis or of filling bone defects comprising the step of implanting a [means] composition according to claim 8 into living beings.

23. (Twice amended) [Method] A method according to claim 21, wherein the ceramic carrier materials are selected from the group consisting of hydroxylapatite, calciumphosphate, aluminum oxide, and ionomer cement.

24. (Twice amended) [Method] A method according to claim 21, wherein the metallic carrier material is titanium or a titanium alloy.

25. (Twice amended) [Method] A method according to claim 21, wherein the [nometallic] nonmetallic carrier material is carbon.

26. (Twice amended) [Method] A method according to claim 21, wherein large bone defects are filled.

27. (Twice amended) [Method] A method according to claim [8] 21, wherein the polymer is derived from natural monomers taken from the group consisting of amino acids, [glutomic] glutamic acid, lactic acid, hydroacetic acid, and copolymers thereof.

28. (Twice amended) [Method] A method according to claim 27, wherein the polymer is a polylactate.

29. (Twice amended) [Method] A method according to claim 22, wherein the polymer is derived from natural monomers taken from the group consisting of amino acids, [glutomic] glutamic acid, lactic acid, hydroacetic acid, and copolymers thereof.

30. (Twice amended) [Method] A method according to claim 29, wherein the polymer is a polylactate.

31. (Twice amended) [Means] A composition according to claim 8, wherein the carrier comprises a lattice structure for receiving the active ingredient complex therein.

32. (Twice amended) [Method] A method according to claim 15, wherein the carrier comprises a lattice structure for receiving the active ingredient complex therein.

33. (Twice amended) [Method] A method according to claim 21, wherein the carrier comprises a lattice structure for receiving the active ingredient complex therein.

34. (Amended) [Means] A composition according to claim 8, wherein the carrier is [a] collagen coated with the active ingredient complex.

35. (Amended) [Method] A method according to claim 15, wherein the carrier is a collagen coated with the active ingredient complex.

38. (Amended) [Means] A composition according to claim 8, wherein said [growth/maturation agent] growth or maturation component is a cytokine.

[38] 39. (Amended) [Method] A method according to claim 15, wherein said [growth/maturation agent] growth or maturation component is a cytokine.